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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,083	01/11/2006	Tatsuhisa Watanabe	050779	7273
23850 7590 10/05/2009 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005			EXAMINER RIGGS II, LARRY D	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 10/05/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,083

Applicant(s)

WATANABE ET AL.

Examiner

LARRY D. RIGGS II

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendments filed 01 June 2009 are acknowledged and entered.

Status of Claims

Claims 1-17 are cancelled. Claims 18-34 are currently pending and under consideration.

Withdrawn Rejections/Objections

The rejection of claims 18, 19, 22-27 and 30-33 under 35 U.S.C. §102(b) over Toshiba, in the Office action mailed 05 March 2009 is withdrawn in view of the amendments filed 03 01 June 2009.

The rejection of claims 18-20, 22-28 and 30-33 under 35 U.S.C. §103(a) over Toshiba in view of Loki et al., in the Office action mailed 05 March 2009 is withdrawn in view of the amendments filed 03 01 June 2009.

The rejection of claims 18, 19, 21-27, 29 and 30-33 under 35 U.S.C. §103(a) over Toshiba in view of Kataoka et al., in the Office action mailed 05 March 2009 is withdrawn in view of the amendments filed 03 01 June 2009.

The rejection of claims 18, 19, 22-27 and 30-34 under 35 U.S.C. §103(a) over Toshiba, in the Office action mailed 05 March 2009 is withdrawn in view of the amendments filed 03 01 June 2009.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or

newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims 26-33 are drawn to a method of confirming a validity of result of clinical examination of a part of a subject for a clinical examination. The instant claims are drawn to the abstract process steps of receiving present and previous data, storing a plurality of reference patterns, selecting a reference pattern matching the present data and previous data, calculating a value indicative of a distance between a position between the reference patterns in the reference patterns and determining a validity of the present data based on the value.

The Supreme Court has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See in re Bilski 88 USPQ2d 1385 (Fed. Cir. 2008) and in re Comiskey 89 USPQ2d 1655 (Fed. Cir. 2009).

See also Benson, 409 U.S. at 70; Diehr, 450 U.S. at 192; see also Flook, 437 U.S. at 589 n.9; Cochrane v. Deener, 94 U.S. 780, 788 (1876).

The instant method claims 26-33 do not recite or inherently involve any transformation of an article, therefore the Examiner must determine if the instant claims have a tie to a particular machine or apparatus. Instant claims 26-33 do not recite any limitation that ties the recited abstract process to any particular machine or apparatus.

Nominal or token recitations will not suffice, E.g. displaying, inputting, obtaining, See Ex parte Langemyr (May 28, 2008). Applicants are cautioned against introduction of new matter in an amendment.

Claims 18-25 recite a "device for confirming a validity of result..." comprising "a receiving unit configured to receive", "a storing unit configured to store", "a selecting unit configured to select", "a calculating unit configured to calculate" and "a determining unit configured to determine".

The specification on pages 10-14 discloses relationships of the units with functions, there are no hardware associated with the above units. Thus at least one embodiment of the invention may be implemented by software. Thus, the "units configured to" perform particular functions, recited in claim 18 encompass software (a program) only. Programs, per se, are not patent eligible subject matter, therefore claim 18 is rejected for this reason.

Claim 34 is drawn to a computer readable recording medium comprising stores a computer program for making a computer execute. The instant specification does not explicitly define the scope of the limitation of "computer readable storing medium." The computer program product/computer readable media is not limited to a physical embodiment and may read on carrier waves and other nonstatutory media. See, e.g., *In re Nuijten*, Docket no. 2006-1371 (Fed. Cir. Sept. 20, 2007)(slip. op. at 18)("A transitory, propagating signal like Nuijten's is not a process, machine, manufacture, or composition of matter.' ... Thus, such a signal cannot be patentable subject matter."). Therefore claim 34 is rejected for this reason.

Response to Arguments

Applicant's arguments filed 01 June 2009 have been fully considered but they are not persuasive.

Regarding claims 26-33, Applicants argue that the clinical data obtained from a clinical examination represents real world tangible thing, i.e. properties of actual physical matter. Applicants argue that the present invention transforms data that is representative of physical objects or substances.

In response, it is not agreed that a receiving data, storing data, matching reference patterns, calculating a value indicative of a distance, and determining the validity of data based on said value involves a transformation of data as set forth in the recent en banc decision of *In re Bilski*. As set forth and reiterated from the instant rejection, the data manipulation set forth in the instant claims does not involve any transformation of a particular article or things as set forth in *In re Bilski*. Further, the

instant claims do not involve any transformation of data representative of physical objects, but rather sets forth a series of abstract and computational steps that require the input of a initial set of data. Such data is not transformed, but rather used as input for an abstract set of computation and determination steps. Therefore, Applicants' arguments are not persuasive.

All other rejections under 35 U.S.C. 101 are newly applied.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 19, 21-27, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toshiba et al. (EP 0389992) in view of Geva et al. (US 2004/0073098).

The instant claims are drawn to a method of confirming a validity of result of clinical examination of a part of a subject for a clinical examination comprising the steps of receiving present and previous data in time, storing a plurality of reference patterns, selecting a reference pattern matching the present data and previous data in the reference patterns, calculating a value indicative of a distance between a position between the reference patterns and determining a validity of the present data.

Regarding claims 18, 22, 26, 30 and 34 Toshiba shows a method and apparatus for analyzing the validity of medical examination data, (page 2, lines 27-40; Figures 1-2). Toshiba shows receiving thousands of sets of present and previous medical examination data with corresponding teaching data stored in order of acquisition (time), (page 4, lines 30-33), medical examination data and teaching data associated with a group (pattern) (page 5, lines 10-28). Toshiba shows calculating a value indicative of whether the medical examination data is valid or if the medical examination data should be obtained again by re-examination based on previous data (i.e. judgments learned at the initial learning of the neural network, (page 4, lines 6-26).

Toshiba does not show reference patterns classified into a plurality of levels, first pattern best matching with present data and second reference best matching with previous data or calculating a distance between a position of the first and second reference patterns.

Geva et al. shows a method that obtains a patient's specific heartbeat pattern, corresponds the patient's pattern with a particular reference heartbeat pattern from a plurality of heartbeat patterns and utilizes additional new heartbeat patterns for re-averaging the person's unique viable heartbeats according to predetermined criteria, (paragraphs 17, 18, 29, 30, 98-105). Geva et al. shows with two time series, utilizing the Generalized Likelihood Ratio (GLR), that compares the statistical properties to the two series and outputs a value which represents the statistical difference (distance) between the two series, (paragraph 174). Geva et al. shows software for executing steps of the method, (paragraphs 97-105).

Regarding claims 19, 27, Toshiba shows each set of medical examination data corresponding to a specifically modified teaching data, (page 4, lines 30-57).

Regarding claims 21 and 29, Geva et al. shows waveform data, (paragraph 108, Figure 11).

Regarding claims 23, 31, Toshiba displays when the medical examination data does not meet a particular value and there is a need for a re-examination, (page 4, lines 19-26).

Regarding claims 24, 32, Toshiba shows stored groups of teaching data that correspond to a particular group of medical examination data, (page 5, lines 19-28).

Regarding claims 25, 33, Toshiba shows stored ranges of values that the value of the medical examination data corresponding teaching data can be compared, (page 6, lines 27-33).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method and system of confirming a validity of result of clinical examination of a part of a subject for a clinical examination by Toshiba with the method and system of analysis of biomedical signals of a patient by Geva et al. because Geva et al. shows analysis of several physiological signals and introduce to a clinician already-correlated data so as to eliminate artifacts, noise, etc. to provide more accurate and well characterized selected physiological events and save the clinician analyzing/interpretation time, (paragraph 5).

Claims 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toshiba et al., (EP 0389992) in view of Geva et al. (US 2004/0073098) as applied to claims 18, 19, 22-27, 30-34 above, in view of Loki et al. (Japan Association of Medical Information, 2002, 14 November, 211-213), IDS, received 11 January 2006.

The instant claims 20 and 28 depend from claims 18 and 26 respectively, with the extra limitation that the reference patterns include image data.

Toshiba et al. in view of Geva et al. is applied to claims 18, 19, 21-27 and 29-34 above.

Toshiba et al. in view of Geva et al. does not show reference patterns that include image data.

Loki et al. shows the relationships between leukocyte-scattergrams and clinical data, (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method and system of confirming a validity of result of clinical examination of a part of a subject for a clinical examination by Toshiba by comparing the medical examination data with leukocyte-scattergrams of Loki et al. because Toshiba shows the importance of obtaining differing groups of teaching data that correspond with different types of medical examination data, (page 5, lines 10-18) and a person of ordinary skill in the art would understand that teaching data that more closely approximate to the medical examination data would result in better determination of the validity of the present medical examination data. Therefore, one of ordinary skill in the art would recognize the claimed process as a combination of routine applications that are well known the art that and produce no more than expected results.

Response to Arguments

Applicant's arguments filed 01 June 2009 have been fully considered.

Applicants argue that Toshiba does not calculate a value indicative of a distance between a position of the medical examination data and teacher data in the reference patterns. Toshiba does not mention a position of teacher data in the reference patterns or a position of distance in the reference patterns.

All rejections under 35 U.S.C. 103(a) are newly applied and all limitations of the instant claims are met by the currently cited art. See above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/
Primary Examiner, Art Unit 1631

/LDR/
Larry Riggs

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